MAY - 1 2003

Smith & Nephew, Inc.
Summary of Safety and Effectiveness: Orthopaedic Cable

Contact Person and Address
Kanu Vadodaria
Senior Regulatory/Clinical Affairs Specialist
Smith & Nephew, Inc., Orthpopaedics Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6261

Date of Summary: April 11, 2003

K031162

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Name of Device: Smith & Nephew Orthopaedic Cable
Common name: Orthopedic Cabling system

Device Classification name:
21 CFR 888.3010 Bone fixation cerclage – Class II

Substantially Equivalent Legally Marketed Devices

The substantial equivalence of the Smith & Nephew Orthopaedic Cabling System is based on the equivalence in intended use, materials, design, operational principles and indications to the following predicate devices – Smith & Nephew's Orthopaedic Cable Systems (K842977, K875156, K924141), Biomet's BMP Cable System (K982545), Howmedica's Dall-Miles Cable System (K971741), Pioneer's Cerclage Cable with Hex Button (K974016), and Zimmer's Cable-Ready Cable Grip System.

Device Description
The Smith & Nephew Orthopaedic Cabling System consists of: a cable with or without clamps or swages; trochanteric grips with or without clamp plates.

Indications for Use:

Cable Implants:
General orthopaedic repair procedures including patella fractures, general cerclage, trochanteric reattachment, femur and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intra-medullary nailing and screwing fixation techniques.

Trochanteric Grips:
Trochanteric reattachment whenever the trochanter is osteomized in any of the procedures listed below:
1. Primary total hip arthroplasty.
2. Revision total hip arthroplasty.
3. Any procedure using anterolateral or lateral approaches.

Technological and Performance Characteristics:
All predicate devices use cables, swages (clamps) and trochanteric grips as a system for bone fracture fixation. Each system uses accessory instruments to provide proper tension and compression to lock the cable. The Smith & Nephew Orthopaedic Cabling System uses similar technology to achieve proper bone fracture fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2003

Mr. Kanu Vadodaria
Senior Regulatory/Clinical Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K031162
Trade/Device Name: Smith & Nephew Orthopaedic Cabling System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: April 11, 2003
Received: April 14, 2003

Dear Mr. Vadodaria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement
Smith & Nephew Orthopaedic Cabling System

510(k) Number (if known): K031162

Device Name: Smith & Nephew Orthopaedic Cabling System

Indications for Use:

a) General orthopaedic repair procedures including patella fractures, general cerclage, trochanteric reattachment, femur and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intra-medullary nailing and screwing fixation techniques.

b) Trochanteric reattachment whenever the trochanter is osteomized in any of the procedures listed below.
   1. Primary total hip arthroplasty.
   2. Revision total hip arthroplasty.
   3. Any procedure using anterolateral or lateral approaches.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 5/1/03